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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,121	06/13/2000	JEFFREY SCHLOM	2026-4266US1	9401

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EXAMINER	
DECLOUX, AMY M	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 12/18/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/529,121	Schlom et al.
Examiner	**Art Unit**
DeCloux, Amy	1644

-- The MAILING DATE f this communication appears on th cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Nov 27, 2001*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-45* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-45* are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Paula Hutzell, Supervisory Patent Examiner at paula.hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

1. Applicant's submission of the instant application as a 371 is acknowledged, however Claim 1 does not provide a technical feature that is distinguished over the prior art, as evidenced by an NCBI blast search which shows the 1988 submission of a CEA precursor protein which comprises the sequence YRSGENLNL at positions 249-257 . YRSGENLNL has at least one amino acid substitution at a non MHC anchor position and absent evidence to the contrary acts as an agonist. Therefore, the instant invention lacks Unity of Invention.

2. Restriction is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I. Claims 1-19, drawn to an embodiment of a peptide agonist, a pharmaceutical composition thereof and a kit, and Claims 30-31, drawn to an embodiment of a method for treating a host having a tumor expressing CEA comprising introducing CTLs specific for CEA and at periodic intervals introducing at least one peptide agonist,

Group II. Claims 20-29, drawn to an embodiment of an isolated DNA, a vector and a host cell,

Group III. Claims 32-36, drawn to an embodiment of a method of inhibiting a CEA epitope expressing carcinoma comprising administering a peptide agonist of claim 1,

Group IV. Claims 32 and 37, drawn to an embodiment of a method of inhibiting a CEA epitope expressing carcinoma comprising administering a peptide agonist of claim 1 and a vector comprising the gene encoding CEA,

Group V. Claim 38, drawn to an embodiment of a method of inhibiting a CEA epitope expressing carcinoma comprising adoptively transferring the CEA epitope or agonist peptide specific cytotoxic T lymphocytes alone or in combination with the agonist peptide of Group I , wherein said CTLs were generated in vitro,

Group VI. Claim 39, drawn to an embodiment of a method of inhibiting a

CEA epitope expressing carcinoma comprising generating CEA epitope or agonist peptide -specific CTLs in vivo by administration of an effective amount of an agonist peptide ,

Group VII.Claim 39, drawn to an embodiment of a method of inhibiting a CEA epitope expressing carcinoma comprising generating CEA epitope or agonist peptide -specific CTLs in vivo by administration of an effective amount of a vector encoding CEA,

Group VIII.Claim 39, drawn to an embodiment of a method of inhibiting a CEA epitope expressing carcinoma comprising generating CEA epitope or agonist peptide -specific CTLs in vivo by administration of an effective amount of agonist peptide pulsed antigen presenting cells,

Group IX.Claims 40-41, drawn to an embodiment of a peptide comprising an antagonist of a SEQ ID NO:1, and a pharmaceutical composition thereof,

Group X.Claims 42-43, drawn to an embodiment of a method of inhibiting CEA-specific immune responses comprising administering a peptide comprising an antagonist of a SEQ ID NO:1,

Group XI. Claims 44-45, drawn to an embodiment of a peptide pulsed cell comprising an antigen presenting cell pulsed with a peptide of Group I.

Note: Each claim will be examined only to the extent of the elected invention.

3. The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

4. Groups I, III-VIII and X are unique methods. Groups I/III-VIII and X differ with respect to their endpoints. Groups I, and III-VIII have essentially the same endpoints, but differ with respect to their respective ingredients and/or process steps. Therefore, Groups I, III-VIII and X do not have the same corresponding technical feature.

5. Groups I/II/IX/XI are unique products, being drawn to a peptide agonist, a DNA, a peptide antagonist and a peptide pulsed cell. The products of Groups I/II/IX/XI differ with respect to their physicochemical and biological properties and therefore do not have the same corresponding technical feature.

6. Because these inventions I-XI are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and because a search of the non patent literature of any of these distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the Examiner, restriction for examination purposes as indicated is proper.

7. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In order for more than one species to be examined, the appropriate additional examination fees must be paid. The species are as follows:

A. Regarding all groups:

a method or product comprising **one specific sequence,** such as one of the SEQ ID NO:s 3-18.

AND FURTHER

B. Regarding Group I:

a specific immunostimulatory molecule(s) such as one recited in claim 9.

a specific HLA Class I molecule, such as HLA-A2 disclosed on page 32 of the instant specification, such as one recited in claim 5,

a specific CEA epitope such as one disclosed on page 11 of the instant specification,

a specific tumor such as one of the carcinomas recited in claim 36.

C. Regarding Group II:

a vector encoding a specific peptide, such as one recited in claim 5 ,

a specific HLA Class I molecule, such as HLA-A2 disclosed on page 32 of the instant specification.

D. Regarding Groups III or V

a specific immunostimulatory molecule, such as one recited in claim 34,

a specific carcinoma cell such as one of the carcinomas recited in claim 36.

E. Regarding Group V

a specific carcinoma cell such as one of the carcinomas recited in claim 36.

F. Regarding Group XI

a specific antigen presenting cell such as one recited in claim 45.

13. Applicant is required, in response to this action, to elect a specific species to which the claims shall be restricted if no generic claim is finally held to be allowable. The response must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

14. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

15. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

16. Claims 1-45 are generic.

17. The species are distinct each from the other because the encompassed products each peptide, each nucleic acid, each immunostimulatory molecule, each class I molecule and each carrier differ with respect to their physicochemical properties, and each of the tumors have different etiologies, so therefore said species do not have the same corresponding technical feature.

18. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

19. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers **other than elections** related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located In Crystal Mall 1. The faxing of such papers must conform with the notice published In the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.
Amy DeCloux, Ph.D.
Patent Examiner

Serial No. 09/529,121
Art Unit 1644

Group 1640
Technology Center 1600
December 17, 2001

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644